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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANDREA FORMENTI and FILIPPO FORMENTI[1]

Appeal 2016-005792
Application 13/580,437
Technology Center 1600

Before MELANIE L. McCOLLUM, RICHARD J. SMITH, and DAVID COTTA, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of treating inflammation in animals. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

Background

"Non-steroidal anti-inflammatory drugs (NSAIDs) are one of the classes of drugs most commonly used in current out-patient practice to treat

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[1] According to Appellants, the real party in interest is FORMEVET S.R.L. (Br. 3.)

inflammation and pain. . . . One of the main limitations of their use is the appearance of side effects, mainly affecting the gastrointestinal tract, kidneys, haemostatic system, etc. . . . Firocoxib is a member of the category of [NSAIDs] belonging to the coxib group." (Spec. 3, ll. 18–20 and 25–27; 4, ll. 21–22.)

"Opioids are a group of drugs with central analgesic activity, which are used to treat moderate to severe pain. . . .Tramadol can be defined as a centrally-acting analgesic . . . and combines rapid activity with fewer and less serious side effects than other opioids." (*Id.* at 4, l. 26–5, l. 4.)

Claims on Appeal

Claims 2–6 are on appeal.[2] (Claims Appendix, Br. 17.) Claim 2, the only independent claim, is illustrative and reads as follows:

2. Method of treating inflammation in animals in need thereof comprising

preparing a medicament comprising a combination of Tramadol and Firocoxib;

administering an effective dose of said combination to said animals, said Firocoxib being administered below a minimum effective anti-inflammatory dose; and

treating said inflammation.

Examiner's Rejections

1. Claims 2–6 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Chen I.[3] (Ans. 3–4.)

2. Claims 2–6 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Chen II.[4] (*Id.* at 4–5.)

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[2] Claim 1 is withdrawn. (Final Act. 1, dated Sept. 25, 2015.)
[3] Chen et al., US 2007/0020335 A1, pub. Jan. 25, 2007 ("Chen I").
[4] Chen et al., US 2008/0220079 A1, pub. Sept. 11, 2008 ("Chen II").

ISSUE

Whether a preponderance of evidence of record supports the Examiner's rejections under 35 U.S.C. § 103(a).

ANALYSIS

Both of the obviousness rejections are based on similar teachings from Chen I and Chen II. (Ans. 3–5.) In particular, the Examiner finds that both references teach methods for reducing pain or fever (inflammation) in an animal, such as a dog or cat, using a composition comprising tramadol and an NSAID such as firocoxib, at certain dosages. (*Id.*) Appellants argue that Chen I and Chen II fail to provide the rationale to sustain a *prima facie* case of obviousness because those references fail to suggest that a low, ineffective dose of firocoxib exhibits "anti-inflammatory activity when administered with an analgesic dose of Tramadol." (Br. 14 and 16.)[5]

The Examiner bears the initial burden of establishing a prima facie case of obviousness, and has not done so. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). A prima facie case of obviousness "requires a suggestion of all limitations in a claim," *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003), and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Here, the Examiner fails to establish that Chen I or Chen II suggest the limitation of "said Firocoxib being administered below a minimum effective anti-inflammatory dose," and fails to provide a persuasive reason why a person of ordinary skill in the

[5] Appellants rely on the same arguments for Rejection No. 2 (Chen II) as advanced in connection with Rejection No. 1 (Chen I). (Br. 16.)

art would have been prompted to use "below a minimum effective anti-inflammatory dose" in a method for treating inflammation.

In this case, Appellants rely on test data, illustrated in Figure 1 of the Specification, and a Declaration of Paola Sacerdote[6] to establish that tramadol is a pain medication that is not known for its inflammatory activity, and that a sub-effective dose of firocoxib alone similarly fails to provide a sufficient anti-inflammatory effect. (Br. 6–9; Decl. ¶¶ 11–14.) However, according to Appellants, the combination recited in claim 2 provides an anti-inflammatory effect, albeit with a sufficiently low dose of firocoxib to avoid its undesirable side effects. (Br. 6, 9; Decl. ¶¶ 25 and 45.)

The Examiner does not point to any teaching or suggestion in Chen I or Chen II of administering the NSAID (i.e. firocoxib) at below a minimum effective anti-inflammatory dose. Rather, the Examiner states that "it would be obvious to lower the concentration of a drug [firocoxib] when in combination with another drug [tramadol] that provides the same efficacy versus the same drug as a monotherapy." (Ans. 7.) However, claim 2 recites a method of treating *inflammation* by combining tramadol, which is not known as an anti-inflammatory, with firocoxib at "below a minimum effective anti-inflammatory dose." (Br. 17.) The Examiner does not adequately explain why such a combination would be expected to treat inflammation.

We are persuaded that neither Chen I nor Chen II teach or suggest all of the limitations of claim 2, and thus reverse the rejection of claims 2–6.

[6] Declaration of Paola Sacerdote, filed Jan. 22, 2015 ("Decl.").

CONCLUSION OF LAW

A preponderance of evidence of record fails to support the Examiner's rejections of claims 2–6 under 35 U.S.C. § 103(a) based on Chen I or Chen II.

SUMMARY

We reverse the rejections of all claims on appeal.

REVERSED